

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:

Applicant : Balwani *et al.*  
Serial Number : Unassigned  
Filed : September 17, 2003  
Title : DECONGESTANT / ANTIHISTAMINIC /  
EXPECTORANT COMPOSITIONS  
Examiner : Unassigned  
Art Unit : Unassigned  
Attorney Docket No. : 452005.150

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

September 17, 2003

**INFORMATION DISCLOSURE STATEMENT**

SIR:

Pursuant to 37 C.F.R. §1.56(a), Applicant(s) hereby cite(s) the enclosed documents listed on the attached copy of Form PTO-1449 which may be material to the patentability of the above-identified application.

This Information Disclosure Statement is filed in accordance with the paragraph of 37 CFR §1.97 indicated below:

  X   §1.97(b) This Information Disclosure Statement is filed:

- (1) Within three months of the filing date of a national application; OR
- (2) Within three months of the date of entry of the national stage of an international application; OR
- (3) Before the mailing of a first Office Action on the merits.  
No fee or statement is required.

\_\_\_§1.97(c) This Information Disclosure Statement is filed after the period specified in paragraph (b) above, but before the mailing date of either:

- (1) A Final Action or under 37 CFR §1.113; OR
- (2) A Notice of Allowance under 37 CFR §1.311; AND

is accompanied by either: (check one)

\_\_\_ The statement as specified in 37 CFR §1.97(e) set out below;  
OR

\_\_\_ The fee of \$180.00 under 37 CFR §1.17(p).

\_\_\_§1.97(d) This Information Disclosure Statement is filed after the mailing date of either:

- (1) a Final Action or under 37 CFR §1.113; OR
- (2) A Notice of Allowance under 37 CFR §1.311;

BUT filed on or before payment of the Issue Fee; AND

is accompanied by:

- (1) The statement as specified in 37 CFR §1.97(e) as set forth below; AND

\_\_\_ The fee of \$180.00 under 37 CFR §1.17(p).

\_\_\_§1.97(e) The undersigned Attorney hereby states that:

\_\_\_ each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing date of this Information Disclosure Statement;

or

\_\_\_ no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, or to the knowledge of the undersigned Attorney after making reasonable inquiry, was known to any individual designated in 37 CFR §1.56(c) more than three months prior to the filing date of the Information Disclosure Statement.

The Commissioner is authorized to charge payment of any fees associated with this communication or credit any overpayment to Deposit Account No. 03-0678.

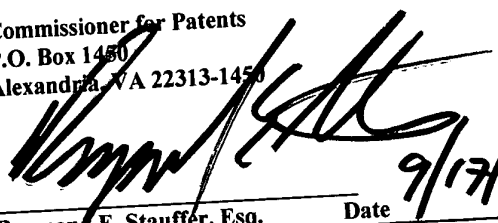
Serial No: Unassigned  
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**CERTIFICATE OF MAILING**

Deposit Date: September 17, 2003

I hereby certify that this paper and the attachments hereto are being deposited today with the U.S. Postal Service with sufficient postage as First Class Mail to Addressee, under 37 CFR 1.8, on the date indicated above addressed to:

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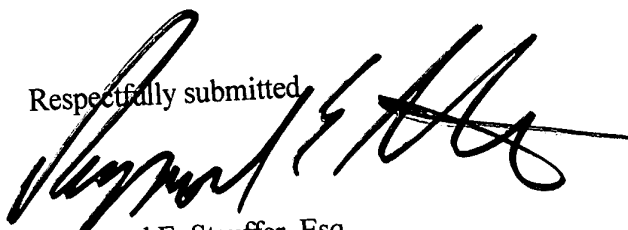
  
Raymond E. Stauffer, Esq.

Date

9/17/03

#194922 v1 - no fee ids

Respectfully submitted



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|   |  |   |          |                                  |                  |                           |                |
|---|--|---|----------|----------------------------------|------------------|---------------------------|----------------|
| Form PTO-1449<br><br><b>INFORMATION DISCLOSURE STATEMENT</b>  |  |   |          | Atty. Docket:<br>452005-150      |                  | Serial No.:<br>Unassigned |                |
|   |  |   |          | Applicant: Bulwani <i>et al.</i> |                  |                           |                |
|   |  |   |          | Filing Date: September 17, 2003  |                  | Group: Unassigned         |                |
| <b>U.S. PATENT DOCUMENTS</b>  |  |   |          |                                  |                  |                           |                |
| Examiner<br>Initial   |  | Document<br>Number  | Date     | Name                             | Class            | Sub-<br>Class             | Filing<br>Date |
|   |  | 6,462,094   | 10/8/02  | Dang et al.                      | 514              | 849                       | 8/22/01        |
|   |  | 6,417,206 B1  | 7/9/02   | Leflein et al.                   | 514              | 352                       | 1/26/01        |
|   |  | 6,306,904 B1  | 10/23/01 | Gordziel                         | 514              | 530                       | 7/25/00        |
|   |  | 6,287,597 B1  | 9/11/01  | Gordziel                         | 424              | 464                       | 3/12/99        |
|   |  | 6,037,358   | 3/14/00  | Gordziel                         | 514              | 357                       | 3/24/99        |
|   |  | 5,807,579   | 9/15/98  | Vilkov et al.                    | 424              | 469                       | 11/14/96       |
|   |  | 5,663,415   | 9/2/97   | Chopdekar et al.                 | 560              | 68                        | 6/28/96        |
|   |  | 5,599,846   | 2/4/97   | Chopdekar et al.                 | 514              | 653                       | 6/28/96        |
|   |  | 5,164,398   | 11/17/92 | Sims et al.                      | 514              | 282                       | 4/1/91         |
|   |  | 4,601,714   | 7/22/86  | Burnhill                         | 604              | 286                       | 3/7/84         |
| <b>FOREIGN PATENT DOCUMENTS</b>   |  |   |          |                                  |                  |                           |                |
| Examiner<br>Initial   |  | Document<br>Number  | Date     | Country                          | Class            | Sub-<br>Class             | Translation    |
|   |  | 64,007,786<br>(abstract)  | 8-31-93  | JP                               | _____            | _____                     |                |
|   |  | 06287144  | 01-02-95 | JP                               | _____            | _____                     |                |
|   |  | 39007786  | 05-18-64 | JP                               | _____            | _____                     | YES            |
| <b>OTHER (Including Author, Title, Date, Pertinent Pages, etc.)</b>   |  |   |          |                                  |                  |                           |                |
|   |  | Weiler et al., "Randomized, double blind, parallel groups, placebo-controlled study of efficacy and safety of Rynatan in the treatment of allergic rhinitis using an acute model," <i>Annals of Allergy</i> , vol. 64(1): 63-67 |          |                                  |                  |                           |                |
|   |  | Goldberg et al., "Evaluation of a Prolonged Action Oral Antihistaminic Preparation as Treatment for Allergic Disorders," <i>Clinical Medicine</i> , vol. 72(9): 1475-1479.  |          |                                  |                  |                           |                |
|   |  | TRIPLE TANNATE, Drug Launches (doc. #: 0182701) 5/99  |          |                                  |                  |                           |                |
|   |  | TUSSI-12, Drug Launches (doc. #: 0179128) 3/99  |          |                                  |                  |                           |                |
|   |  | TUSSI-12, Drug Launches (doc. #: 0176901) 12/98   |          |                                  |                  |                           |                |
| Examiner:   |  |   |          |                                  | Date Considered: |                           |                |
| <b>EXAMINER:</b> Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant. |  |   |          |                                  |                  |                           |                |

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| <b>U.S. PATENT DOCUMENTS</b>  |  |   |          |                                  |                  |                           |                |
| Examiner<br>Initial   |  | Document<br>Number                                      | Date     | Name                             | Class            | Sub-<br>Class             | Filing<br>Date |
|   |  | B1 4552,899   | 10/20/92 | Sunshine <i>et al.</i>           | 514              | 568                       | 4/9/84         |
|   |  | 4,552,899   | 11/12/85 | Sunshine <i>et al.</i>           | 514              | 568                       | 4/9/84         |
|   |  | 3,061,517   | 10/30/62 | Walter                           | 167              | 65                        | 2/16/62        |
|   |  | 3,018,221   | 1/23/62  | Millar <i>et al.</i>             | 167              | 65                        | 3/28/58        |
|   |  | 2,798,024   | 7/2/57   | Zappas <i>et al.</i>             | 167              | 82                        | 6/2/54         |
|   |  | 2,757,124   | 7/31/56  | Wolff                            | 167              | 82                        | 3/8/52         |
|   |  | 20010011104   | 8/2/01   | Gordziel                         | 514              | 653                       | 12/11/98       |
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|   |  |   |          |                                  |                  |                           |                |
|   |  |   |          |                                  |                  |                           |                |
| <b>OTHER (Including Author, Title, Date, Pertinent Pages, etc.)</b>   |  |   |          |                                  |                  |                           |                |
|   |  | R-TANNATE, Drug Launches (doc. #: 0172212) 8/98         |          |                                  |                  |                           |                |
|   |  | TRIPLE TANNATE, Drug Launches (doc. #: 0163340). 1/98   |          |                                  |                  |                           |                |
|   |  | ATROHIST, Drug Launches (doc. #: 0154800). 5/97         |          |                                  |                  |                           |                |
|   |  | GELHIST, Drug Launches (doc. #: 015445). 5/97           |          |                                  |                  |                           |                |
|   |  | PHENATAN, Drug Launches (doc. #: 0149758) 1/97          |          |                                  |                  |                           |                |
|   |  | TRIOTANN, Drug Launches (doc. #: 0136052) 12/95         |          |                                  |                  |                           |                |
|   |  | TRI-TANNATE, Drug Launches (doc. #: 0129566) 6/95       |          |                                  |                  |                           |                |
|   |  | RICOBIN-D, Drug Launches (doc. #: 0129564) 6/95         |          |                                  |                  |                           |                |
|   |  | RICOBID, Drug Launches (doc. #: 0129563) 6/95           |          |                                  |                  |                           |                |
|   |  | QUAD-TUSS TANNATE, Drug Launches (doc. #: 0127440) 4/95 |          |                                  |                  |                           |                |
|   |  | TRI-TANNATE, Drug Launches (doc. #: 0179121) 3/99       |          |                                  |                  |                           |                |
|   |  | TRITAN, Drug Launches (doc. #: 0144945) 9/96            |          |                                  |                  |                           |                |
|   |  | TRI-NATAN, Drug Launches (doc. #: 0110372) 11/93        |          |                                  |                  |                           |                |
|   |  | R-TANNATE, Drug Launches (doc. #: 0110158) 11/93        |          |                                  |                  |                           |                |
|   |  | TRIN TUSS, Drug Launches (doc. #: 0049139) 3/93         |          |                                  |                  |                           |                |
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